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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/562,813	06/14/2006	Oreste Piccolo	281250US0XPCT	6561
22850 7590 06/28/2007 OBLON, SPIVAK, MCCLELLAND, MAIER & NEUSTADT, P.C. 1940 DUKE STREET ALEXANDRIA, VA 22314			EXAMINER CHO, JENNIFER Y	
			ART UNIT 1621	PAPER NUMBER
			NOTIFICATION DATE 06/28/2007	DELIVERY MODE ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/562,813	Applicant(s) PICCOLO ET AL.	
	Examiner Jennifer Y. Cho	Art Unit 1621	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 June 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>12/30/2005</u> . | 6) <input type="checkbox"/> Other: _____ |

Detailed Action

This office action is in response to Applicant's communication filed on 6/14/2006.

Claims 1-20 are pending in this application.

IDS

The information disclosure statement (IDS) filed on 12/30/2005 is acknowledged.

The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Claim Rejections – 35 USC 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1 and 4 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The Applicant has not identified or provided examples of the catalyst "precursor". The specification only briefly describes what the precursor could be, but does not provide any working examples (page 5, second to the

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last paragraph). It is suggested that the Applicant provide examples of the catalyst precursor.

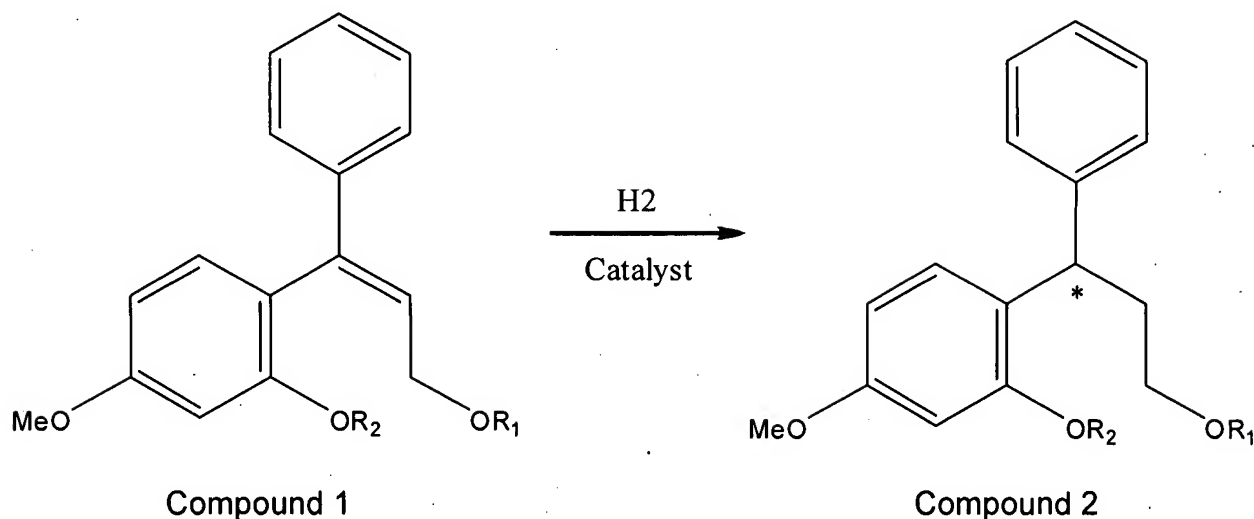
Claim Rejections – 35 USC 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bissel et al. (Tetrahedron: Asymmetry (1995) 6(4) 835-838).

Bissel et al. teaches the asymmetric catalytic hydrogenation of compound 1 to compound 2, using ruthenium catalysts, including Rh(NBD)(Chiraphos)ClO₄ (page 836, table 1, entry 11). The hydrogenation was carried out at 30°C, a pressure of 75-80 bars, at a molar ratio between the catalyst and substrate of 1/20 and in a methanol/methylene chloride solvent (page 836, second paragraph and footnotes of table 1).



Bissel et al. is deficient in the sense that it does not specifically point out Applicant's catalyst support, molar ratio, pressure or tolterodine compound. However, it is the position of the examiner that one of ordinary skill in the art, at the time of the invention, would through routine and normal experimentation determine the optimization of these limitations to provide the best effective variable depending on the results desired. Thus it would be obvious in the optimization process to optimize the catalyst support, molar ratio, pressure and compound. The Applicant does not show any unusual and/or unexpected results for the limitations stated. Note that the prior art provides the same effect desired by Applicant, the enantioselective hydrogenation tolterodine derivatives in good yield.

Therefore, it would be prima facie obvious to one of ordinary skill in the art at the time of the invention, to use the appropriate catalyst support, molar ratio, pressure and tolterodine compound. The expected result would be the enantiomeric enrichment of tolterodine derivatives in high yield.

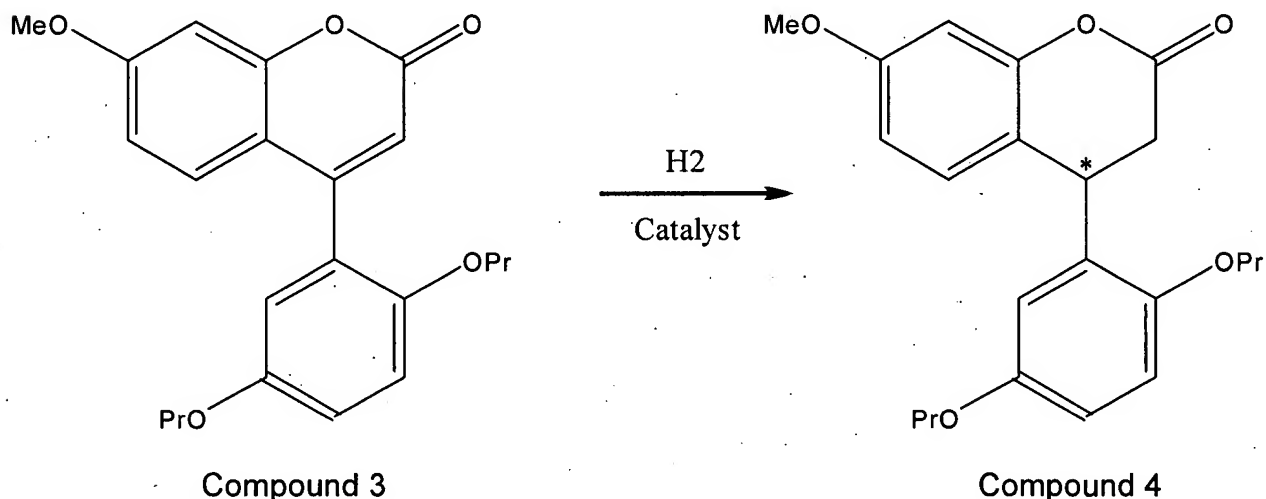
Claim Rejections – 35 USC 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over McGuire et al. (Tetrahedron Letters 40 (1999) 3293-3296).

McGuire et al. teaches the asymmetric catalytic hydrogenation of compound 3 to compound 4 (page 3295, compounds 8 and 9), using ruthenium catalysts, including Rh(NBD)(Chiraphos)ClO₄ (page 3294, table 1, entry 13). The hydrogenation was carried out at 40-50°C (page 3294, first paragraph, line 2), a pressure of 80 psi (5bar) (page 3294, table 1), at a molar ratio between the catalyst and substrate of 1/1000 (0.1 mol%) (page 3294, third paragraph, line 3) and in a methanol solvent (page 3294, table 1).



McGuire et al. is deficient in the sense that it does not specifically point out Applicant's catalyst support or lactone compound. However, it is the position of the examiner that one of ordinary skill in the art, at the time of the invention, would through routine and normal experimentation determine the optimization of these limitations to provide the best effective variable depending on the results desired. Thus it would be obvious in the optimization process to optimize the catalyst support or lactone compound. The Applicant does not show any unusual and/or unexpected results for the limitations stated. Note that the prior art provides the same effect desired by Applicant, the enantioselective hydrogenation of lactone derivatives in good yield.

Therefore, it would be prima facie obvious to one of ordinary skill in the art at the time of the invention, to use the appropriate catalyst support and lactone compound. The expected result would be the enantiomeric enrichment of lactone derivatives with high enantiomeric excess.

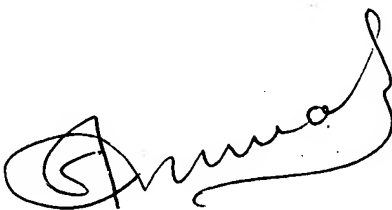
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Y. Cho whose telephone number is (571) 272 6246. The examiner can normally be reached on 9 AM - 6 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on (571) 272 0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Jennifer Cho
Patent Examiner
Art Unit: 1621

for 

Johann Richter
Supervisory Patent Examiner
Technology Center 1600